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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,024	06/24/2003	Bradley G. Thompson	16596-001001	7648
26181	7590	03/08/2005	EXAMINER	
FISH & RICHARDSON P.C. 3300 DAIN RAUSCHER PLAZA MINNEAPOLIS, MN 55402			BROWN, TIMOTHY M	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,024

Applicant(s)

THOMPSON ET AL.

Examiner

Timothy M. Brown

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15 and 23-30, drawn to a method of detecting ras-activated neoplastic cells comprising determining whether a biological sample is permissive for reovirus infection, classified in class 435, subclass 5.
- II. Claims 16-22 and 31-33, drawn to a method of treating a ras-activated neoplasm, classified in class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). Here, the combination (Invention II) does not require does not require the particulars of the subcombination (Invention I) for patentability because administering a therapeutic agent that is specific for ras-activated neoplasms is not old and well known in the art. Also, the subcombination has separate utility such that it can be used to identify neoplasms for other forms of antineoplastic therapy.

Should Applicants elect Invention I, a further election of one of the following groups is required:

- i. Contacting the sample with serotype 3 Dearing strain reovirus
- ii. Contacting the sample with avian reovirus
- iii. Obtaining the sample from one of the cancers listed in claim 8
- iv. Contacting the sample with reovirus
- v. Contacting the sample with adenovirus having a VA1 mutation
- vi. Contacting the sample with vaccinia having a K3L mutation
- vii. Contacting the sample with vaccinia having a E3L mutation
- viii. Contacting the sample with vaccinia having a K3L and a E3L mutation
- ix. Contacting the sample with parapoxvirus orf viruses having a OV20.0L mutation
- x. Contacting the sample with influenza virus having a NS-1 mutation
- xi. Contacting the sample with herpes virus having a gamma 34.5 mutation
- xii. Contacting the sample with vesicular stomatitis virus
- xiii. Contacting the sample with ONYX-015 virus
- xiv. Contacting the sample with Delta24 virus
- xv. Any one of the neoplastic cell phenotypes listed in claim 26

Groups i, ii and v-xiv are unrelated to Group iii. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Here, the viruses of Groups i, ii and v-xiv are not disclosed as capable of being used with the different

types of cancer from Group iii. That is, the viruses are not disclosed as identifying the different types of cancer as ras-activated neoplasms. Moreover, the ability to preferentially infect ras-activated neoplasms provides the listed viruses with a different effect than the cancer types from Group iii. For at least these reasons, the viruses of Groups i, ii and v-xiv are unrelated to the cancer types of Group iii.

Groups i, ii and v-xiv are unrelated to Group xv. As with Group iii, the listed viruses are not disclosed as capable of being used with the listed neoplastic cell phenotypes (i.e. Group xv). Moreover, the function of the listed viruses is to preferentially infect ras-activated neoplasms, and not to serve as a biological sample. Therefore, Groups i, ii and v-xiv are unrelated to Group xv.

Group iii is unrelated to Group xv because of different functions. The function of the cancer types of Group iii is to define a population of patients for obtaining a sample. This is unlike the function of the neoplastic phenotypes of Group xv which classify a type of cancer as belonging to a certain signaling pathway.

The viruses of Groups i, ii and v-xiv are also unrelated to one another. The listed viruses have distinct immunogenicities and each virus infects a unique cell type through divergent viral surface proteins. Groups i, ii and v-xiv are therefore unrelated to one another for having different effects.

Should Applicants elect Invention II, a further election of one of the following groups is required:

- xvi. Avian Reovirus

- xvii. Adenovirus having a VA1 mutation
- xviii. Vaccinia having a K3L mutation
- xix. Vaccinia having a E3L mutation
- xx. Vaccinia having a K3L and a E3L mutation
- xxi. Parapoxvirus orf-viruses having a OV20.0L mutation
- xxii. Influenza virus having a NS-1 mutation; and herpes virus having a gamma 34.5 mutation
- xxiii. Vesicular stomatitis virus
- xxiv. ONYX-015 virus
- xxv. Delta24 virus
- xxvi. Any one of the neoplasms listed in claim 22
- xxvii. Any one of the neoplasm phenotypes listed in claim 32

Groups xvi-xxv are unrelated to Group xxvi for the same reasons cited in the restriction of Groups i, ii and v-xiv and Group iii above.

Groups xvi-xxv are unrelated to Group xxvii for the same reasons cited in the restriction of Groups i, ii and v-xiv and Group xv above.

Groups xvi-xxv are unrelated to Group xxvii for the same reasons as cited in the restriction of Groups iii and xv above.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Conclusion

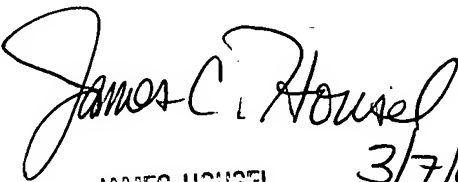
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy M. Brown can be reached on (571) 272-0773. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb


JAMES HOUGEL
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3/7/05